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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/436,060	11/08/1999	James T Kealey	014/002C	6093

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/436,060	KEALEY ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *38 and 39* is/are allowed.

6)☒ Claim(s) *35-37, 40, 41, and 44* is/are rejected.

7)☒ Claim(s) *42 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed July 24, 2007.

Claim 34 has been canceled. Claims 35-37, 40, and 42-44 have been amended.

Claims 35-44 are pending in the instant application.

Claims 35-44 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed May 1, 2007, claims 34-36, 40, and 41 were rejected under 35 U.S.C. 102(e) as being anticipated by Villeponteau et al. [U.S. Patent No. 5,776,679, made of record in the previous Office Action mailed December 22, 2004]. **This rejection is moot** against claim 34 in view of Applicant's Amendment to cancel claim 34, filed July 24, 2007. **This rejection is withdrawn** against claims 35, 36, 40, and 41 in view of the new rejection presented below:

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35, 36, 40, 41, and 44 are rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Villeponteau et al. [U.S. Patent No. 5,776,679, made of record in the Office Action mailed December 22, 2004].

The invention is drawn to a pharmaceutical composition consisting of a polynucleotide in a pharmaceutically acceptable carrier, wherein the polynucleotide:

(a) has a sequence of at least 7 nucleotides that specifically hybridizes to a first nucleotide sequence within an accessible region of the RNA component of human telomerase ("hTR"), wherein the accessible region is selected from nucleotides 137-196, 290-319, and nucleotides 350-380 of hTR (SEQ ID NO:16),

(b) does not hybridize to a second nucleotide sequence within the template region of the hTR, said template region being nucleotide 46-55 of SEQ ID NO:16, and

(c) is effective to inhibit the synthesis of telomeric DNA by telomerase.

It is noted that in the previous Office Action mailed May 1, 2007, at pages 13 and 14, the Examiner indicated that the following invention is free of the prior art:

> An invention drawn to a pharmaceutical composition consisting of a polynucleotide in a pharmaceutically acceptable carrier, wherein the polynucleotide:
>
> (a) has a sequence of at least 7 nucleotides that specifically hybridizes to a first nucleotide sequence within an accessible region of the RNA component of human telomerase ("hTR"), wherein the accessible region is selected from nucleotides 137-196, 290-319, and nucleotides 350-380 of hTR (SEQ ID NO:16),
>
> (b) does not hybridize to a second nucleotide sequence within the template region of the hTR, said template region being nucleotide 46-55 of SEQ ID NO:16, and
>
> (c) is effective to inhibit the synthesis of telomeric DNA by telomerase.

However, after careful reconsideration of the claims, the Examiner realizes that she was mistaken in indicating that said invention was free of the prior art because the invention is actually anticipated or obvious over Villeponteau et al. as discussed below.

Villeponteau et al. disclose a stand-alone PCR primer that contains nucleotides 145-166 of SEQ ID NO:16 (see Villeponteau et al. at primer RC3 or SEQ ID NO:3). Given this high degree of similarity, the PCR primer disclosed by Villeponteau et al. would specifically hybridize to the accessible region of nucleotides 137-196 of Applicant's invention. Villeponteau et al. also disclose that the nucleic acids (e.g. primers) of their invention are useful as pharmaceutical, therapeutic, and diagnostic reagents (see Abstract).

It is noted that Villeponteau et al. do not disclose the exact reagent that the stand-alone primer was resuspended in (e.g. water, buffer, oil emulsion, etc.). However, the instant specification at page 9, lines 25-33 discloses that a

"pharmaceutical acceptable carrier" includes "various types of wetting agents". It is the Examiner's position that clearly, the PCR primer disclosed by Villeponteau et al. was synthesized and resuspended in some type of wetting agent (for example, water or a resuspension buffer) since the primer was later added, volume-wise, to a PCR reaction solution.

Further, since the prior art PCR primer is disclosed as being useful as pharmaceutical, therapeutic, or diagnostic reagents, the prior art primer would then be considered to be a "pharmaceutical composition" as claimed, absent evidence to the contrary. Furthermore, the burden of establishing whether the prior art primer has the further function of acting as a pharmaceutical composition under generally any assay condition falls to Applicant. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). "Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product... This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property

or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Therefore, absent evidence to the contrary, the instant invention is anticipated or obvious over Villeponteau et al.

******

Claims 37 and 44 are rejected under 35 U.S.C. 103(a) as being anticipated by Villeponteau et al. [U.S. Patent No. 5,776,679, made of record in the Office Action mailed December 22, 2004] in view of Nakamaye et al. (Nucleic Acids Research, 1988 Vol. 16:9947-9959, made of record in the Office Action mailed May 1, 2007).

Claim 44 is as described *supra*. Claim 37 is dependent on claim 44 and includes all the limitations of claim 44 with the further limitation wherein said polynucleotide comprises a nucleotide analog or non-naturally occurring nucleotide linkage selected from phosphorothioates, phosphoramidates, methyl phosphonates, chiral-methyl phosphonates, 2-O-methyl ribonucleotides and peptide-nucleic acids.

Villeponteau et al. is relied upon as discussed *supra*.

Villeponteau et al. do not teach wherein the polynucleotide further comprises a non-naturally occurring nucleotide linkage, including a phosphorothioate linkage.

Nakamaye et al. teach an alternative method for direct sequencing of DNA generated by *Taq* polymerase-PCR, via the incorporation of phosphorothioate nucleotides and followed by treatment with an alkylating agents that cleaves specifically at the phosphorothioate positions (see Abstract). Specifically, Nakamaye et al. teach

PCR performed using three normal nucleotides and one phosphorothioate-containing nucleotide resulted in a good yield of PCR product (see Figure 1) that could be successfully and directly sequenced (see page 9954).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a polynucleotide comprising a sequence of at least 7 nucleotides that specifically hybridizes to an accessible region of the RNA component of human telomerase (hTR), wherein the accessible region is nucleotides 137-196 or nucleotides 137-166 of SEQ ID NO:16 of the instant invention using the teachings of Villeponteau et al. It would have been obvious to one of ordinary skill in the art to incorporate a phosphorothioate linkage on said polynucleotide using the teachings and motivation of Nakamaye et al.

One of ordinary skill in the art would have been motivated to make a polynucleotide comprising a sequence of at least 7 nucleotides that specifically hybridizes to an accessible region of the RNA component of human telomerase (hTR), wherein the accessible region is nucleotides 137-196 or nucleotides 137-166 of SEQ ID NO:16 of the instant invention since the prior art taught such a polynucleotide could be used as a primer in the preparation of antisense plasmids for the RNA component of human telomerase, which is important in cloning human telomerase cDNA (see Villeponteau et al.). One of ordinary skill in the art would have been motivated to incorporate a phosphorothioate linkage on said polynucleotide since the prior art has taught that phosphorothioate-containing primers yield PCR products that can be directly sequenced (see Nakamaye et al.).

One of ordinary skill in the art would have expected success at making a polynucleotide comprising a sequence of at least 7 nucleotides that specifically hybridizes to an accessible region of the RNA component of human telomerase (hTR), wherein the accessible region is nucleotides 137-196 or nucleotides 137-166 of SEQ ID NO:16 of the instant invention since Villeponteau et al. taught the successful use and design of such a polynucleotide in the preparation of antisense plasmids for the RNA component of human telomerase. One of ordinary skill in the art would have expected success at modifying the polynucleotide to comprise a phosphorothioate linkage since Nakamaye et al. taught the successful use and design of phosphorothioate-containing primers in PCR and DNA sequencing.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Claims 42 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 42 and 43 are considered free of the prior art since the prior art does not teach or fairly suggest a pharmaceutical composition comprising a polynucleotide in a pharmaceutically acceptable carrier, wherein the polynucleotide:

(a) has a sequence of at least 7 nucleotides that specifically hybridizes to a first nucleotide sequence within an accessible region of the RNA component of human

telomerase ("hTR"), wherein the accessible region is selected from nucleotides 290-319, and nucleotides 350-380 of hTR (SEQ ID NO:16),

(b) does not hybridize to a second nucleotide sequence within the template region of the hTR, said template region being nucleotide 46-55 of SEQ ID NO:16, and

(c) is effective to inhibit the synthesis of telomeric DNA by telomerase.

Allowable Subject Matter

Claims 38 and 39 are allowable. Claims 38 and 39 are considered to be free of the prior art since the prior art does not teach or fairly suggest a polynucleotide consisting of a sequence selected from the group consisting of SEQ ID NOs: 2-14 or pharmaceutical compositions therein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information

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tcg
October 5, 2007

/Terra Cotta Gibbs/